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Our Daughter's Keepers?

An Overview of the Debate Regarding an HPV Vaccination for Men

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This paper is written in satisfaction of the course requirement.

Abstract

Introduction

Until 2006, it had appeared as if genital human papillomavirus (HPV) was an unavoidable risk for sexually active men and women. 20 million people were already infected, and approximately 6.2 million Americans stood to acquire the disease each year.¹ The Center for Disease Control (CDC) estimated that by the age of 50, 80 percent of women will have developed the infection.² While alarming in themselves, these numbers become even more troubling when one considers the effects of genital HPV. Approximately 10 out of the 30 identified types of genital HPV can lead to cervical cancer in women.³ In rarer cases, HPV can also cause cancers of the anus, vagina and vulva.⁴

Enter Gardasil. In 2006, Merck Pharmaceuticals received approval from the Food and Drug Administration (FDA) for its vaccine, Gardasil, which was developed, “to prevent cervical cancer, precancerous genital lesions, and genital warts due to human papillomavirus.”⁵ What was hailed as a critical health measure and a “significant advance in the protection of women’s

¹Ctr. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Genital HPV Infection Fact Sheet 1* (2004), <http://www.cdc.gov/std/HPV/hpv.pdf>.

²*Id.*

³*Id.*

⁴Ctr. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *HPV Vaccine Information for Young Women*, <http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine-young-women.htm> (last visited Mar. 29, 2009).

⁵ Press Release, U.S. Food & Drug Admin., FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health (June 8, 2006), <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>.

health,”⁶ quickly developed into a major legal and ethical controversy. This controversy, pitting those that claim Gardasil is ethically troubling against those who believe the vaccine should be mandatory for all school-children, has recently intensified following Merck’s announcement that it has completed clinical trials and is currently seeking FDA approval to use Gardasil to vaccinate men.⁷

This paper will discuss the challenges that Merck will face in seeking societal and governmental acceptance of an HPV vaccination for men. Part I describes some of the background of the HPV infection, in order to understand what lead Merck to develop the vaccine in the first place. Part II will discuss how the original Gardasil vaccine for women was developed. Part III explains the current status of the vaccine for men. Part IV analyzes the various barriers that Merck will face in convincing the public that men needs to be vaccinated against HPV. It breaks the opposition to the vaccine into two parts- Part A discusses the legal barriers the vaccination will have to overcome, and Part B focuses on the ethical barriers. Finally, Part V speculates about the future of the Gardasil vaccine for men, and the options Merck will have upon FDA approval.

Part I: HPV Background

Genital HPV is a sexually transmitted disease which infects the skin of the penis, the vulva (the area outside of the vagina), the anus, and the linings of the vagina, cervix, or rectum.⁸

⁶*Id.*

⁷Radha Chitale, *Merck Hopes to Extend Gardasil Vaccine to Men*, 101 *Journal of the National Cancer Institute Advance Access* 222 (February 18, 2009).

⁸Ctrs. for Disease Control & Prevention, *supra* note 1, at 1.

Most people who are infected with the disease experience no symptoms.⁹ While many are able to clear the disease on their own, for others, it can develop into genital warts, or worse- the “high risk” strains of the virus can lead to cervical, vulvar, or anal cancers if left undetected.¹⁰

HPV is spread primarily through genital contact.¹¹ Because the virus often has no symptoms, infected individuals may infect their sex partners unknowingly.¹² While condom use can be helpful in preventing the disease, it is not a foolproof method since the infection may occur on parts of the male and female genitals that are not protected by a condom.¹³ The CDC recommends long-term, mutually monogamous relationships, although it acknowledges that even these relationships may be susceptible to the infection since carriers are typically unaware that they have the disease.¹⁴ Another barrier to prevention of the disease is that at present, there are no tests available to diagnose whether men carry the infection. While women are able to be diagnosed with HPV on the basis of abnormal Pap tests (cancer-screening tools which doctors use to look for cervical cancer or pre-cervical cancer changes to the cervix) there are no such screening tools for men.¹⁵

The invention of Pap smear tests significantly reduced the risks of contracting cervical

⁹*Id.*

¹⁰*Id.*

¹¹*Id.*

¹²*Id.*

¹³*Id.* at 2.

¹⁴*Id.*

¹⁵*Id.* at 1.

cancer, since Pap tests can result in early detection of abnormalities caused by the cancer.¹⁶

Unfortunately, Pap smear tests are still not enough to deal with HPV on their own. As discussed above, HPV is still extremely common among sexually active adults. This results in high instances of cervical cancer, both in the United States and abroad. The American Cancer Society estimated that in 2008, approximately 11,070 cases of cervical cancer would be diagnosed in the United States.¹⁷ HPV is detected in 99% of cervical cancer cases.¹⁸ Outside of the United States, the numbers are even more startling. Globally, 470,000 cases of cervical cancer are diagnosed each year, resulting in approximately 230,000 deaths per year.¹⁹ The prevalence of cervical cancer abroad has been attributed to cultures who do not accept the Pap screening process, and the lack of available resources to perform the test on those that do.²⁰ While cervical cancer has been the obvious focus of much of the research surrounding HPV and the Gardasil vaccine, homosexual men are also highly at risk for developing cancers related to HPV. Gay and bisexual men are reportedly 17 times more likely to develop anal cancer than their heterosexual

¹⁶*Id.*

¹⁷American Cancer Society, *What are the Key Statistics About Cervical Cancer?*, http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_cervical_cancer_8.asp?sitearea= (last visited March 29, 2009).

¹⁸Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 Morbidity & Mortality Wkly. Rep. 1,2 (Mar. 23, 2007), available at <http://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf>.

¹⁹Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 Am. J.L. & Med. 159, 164 (2006).

²⁰Richard Roden & T.-C. Wu, *How Will HPV Vaccines Affect Cervical Cancer?*, 6 Nature Revs. Cancer 753, 753 (2006).

counterparts.²¹

Unfortunately, knowledge regarding HPV and its connection to cervical cancer is severely lacking in the United States today.²² A survey done by the National Cancer Institute's Health Information National Trends survey found that only 38.3% of women surveyed had even heard of HPV.²³ Less than 50% of these women knew that HPV caused cervical cancer.²⁴ And while it is certainly possible to clear the infection without treatment, over 80% of those surveyed said that they believed that HPV could not be cured without treatment.²⁵

Part II: Development of Gardasil

Vaccination is often the most cost-efficient method of combating an infectious disease like HPV.²⁶ This understanding, along with the above-mentioned lack of knowledge regarding the HPV infection, combined with the causal association with cervical cancer, the high incidence of HPV throughout the population, and the inability to find an effective means to test for and prevent the spread of HPV among sexually active individuals led Merck to develop the Gardasil

²¹Emedtv.com, *HPV in Men*, <http://hpv.emedtv.com/hpv/hpv-in-men.html> (last visited February 14, 2009)

²²Judith Sites-Poisson, *Setting the Stage: Part One in a Series on the Politics and PR of Cervical Cancer*, CENTER FOR MEDIA & DEMOCRACY, June 26, 2007, <http://prwatch.org/node/6186>.

²³*Id.*

²⁴*Id.*

²⁵*Id.*

²⁶Roden & Wu, *supra* note 20, at 753.

vaccine.²⁷ The vaccine itself is made of self-assembled virus-like particles (VLPs), which closely resemble native HPV particles and thus act as, “antigen[s] that evokes the production of HPV-neutralizing antibodies in the human body.”²⁸ It was developed as a recombinant vaccine (meaning it contains no live virus, like the measles or polio vaccines²⁹), and it does not contain DNA, so it is considered to be non-infectious.³⁰ It is administered via three injections over a six month period.³¹ Immunization is expected to prevent most cases of cervical cancer, although it cannot protect women who were exposed to HPV before receiving the vaccine.³² Merck conducted four studies (one in the United States and three multinational) composed of 21,000 women between the ages of 16 to 26.³³ The results were overwhelmingly positive- although it was not feasible to conduct the study for a long enough period of time to detect whether the vaccine had prevented cervical cancer, according to the FDA, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts.³⁴ Prevention of these precancerous lesions is considered indicative of

²⁷See L. Shi et al., *Gardasil: Prophylactic Human Papillomavirus Vaccine Development-From Bench Top to Bed-Side*, 81 *Clinical Pharmacology & Therapeutics* 259, 261 (2007).

²⁸Amy L. Jonson, American Medical Ass’n Journal of Ethics, *Development of the Human Papillomavirus Vaccine and Guidelines for Its Use*, 9 *Virtual Mentor* 30, 30-33 (January 2007).

²⁹VaccineInfo.net, Vaccine Facts: Conscientious Choice and Informed Consent for Vaccination are Parental Rights, http://www.vaccineinfo.net/immunization/vaccine_facts.shtml (last visited March 24, 2009).

³⁰See Jonson *supra* note 28.

³¹Press Release, *supra* note 5.

³²*Id.*

³³*Id.*

³⁴*Id.*

prevention of the later development of cervical cancer.³⁵ In September 2008, the FDA announced its approval of Gardasil for use in preventing vulvar and vaginal cancers in addition to cervical cancer.³⁶ Jesse L Goodman, the director of the FDA's Center for Biologics Evaluation and Research said, "There is now strong evidence showing that this vaccine can help prevent vulvar and vaginal cancers...While [these] cancers are rare, the opportunity to help prevent them is potentially an important additional benefit from immunization against HPV."³⁷

The FDA approved Gardasil for use in females 9-26 years of age in June of 2006.³⁸ The CDC's Advisory Committee on Immunization Practices (ACIP) quickly followed, recommending the vaccine for girls ages 11-12, but approved its use as early as age 9, and extended it to females up to 26 years of age as well.³⁹ While there are no federal laws governing the immunization of children, the ACIP consists of 15 members appointed by the U.S. Secretary of the Department of Health and Human Services, and their recommendations become CDC policy.⁴⁰ ACIP also resolved to include Gardasil in the Vaccination for Children (VFC) Program, which provides free immunizations to many who are unable to afford vaccination on their own.⁴¹

³⁵*Id.*

³⁶Press Release, U.S. Food & Drug Admin., FDA Approves Expanded Uses for Gardasil to Include Preventing Certain Vulvar and Vaginal Cancers (September 12, 2008), <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html>.

³⁷*Id.*

³⁸Press Release, *supra* note 5.

³⁹Press Release, Office of Enter. Comm'n, Ctrs. for Disease Control & Prevention, CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination (June 29, 2006), <http://www.cdc.gov/od/oc/media/pressrel/r060629.htm>.

⁴⁰*Id.*

⁴¹Sites-Poisson, *supra* note 22.

Approximately 40-45% of the U.S. child population is covered by the VFC.⁴²

Following FDA and CDC approval, individual states began to regulate the use of Gardasil for themselves, primarily through the use of school-entry mandatory vaccination laws. These laws allows the states to regulate the vaccine so it is given to pre-teens, since Gardasil is most effective when it is given before the age of sexual debut.⁴³ In 2007, nearly half of high school students reported having had sexual intercourse, and the median age of first intercourse typically ranges from 17.4 for females, and 16.9 for males.⁴⁴ As a result, school-entry requirements for 11-12 year olds seems to be the best way to reach students before they became sexually active in high school.

In 2006, Michigan became the first state to introduce such legislation.⁴⁵ While the bill was ultimately not enacted by the state legislature, many other states followed suit.⁴⁶ In Texas, Governor Rick Perry bypassed the state legislature altogether by issuing an executive order mandating that all girls become vaccinated before entering the sixth grade.⁴⁷ The executive order, was supposed to have “saved legislators from having to go on record for or against a bill

⁴²*Id.*

⁴³*See* Roden and Wu, *supra* note 20, at 756 (Explaining that this protects young females in the case of abuse or possible non-sexual transmission).

⁴⁴Kaiser Family Foundation, Sexual Health of Adolescents and Young Adults in the United States 1 (September 2008), www.kff.org/womenshealth/upload/3040_04.pdf.

⁴⁵Nat'l Conference of State Legislatures, HPV Vaccine, <http://www.ncsl.org/programs/health/HPVvaccine.htm#hpvlegis> (last visited March 29, 2009).

⁴⁶*Id.*

⁴⁷Ralph Blumenthal, Texas Is First to Require Cancer Shots for Schoolgirls, N.Y. Times, Feb. 3, 2007, at A9.

involving child sexuality.”⁴⁸ In May 2007, Virginia became the first state to successfully pass a law mandating HPV vaccination for school attendance.⁴⁹ As of March 2009, at least 19 states have passed some form of legislation to require, fund or educate the public about the HPV vaccine.⁵⁰

Part III: Getting men vaccinated

In November of 2008, Merck announced that it had completed a study of the efficacy of using Gardasil to prevent genital lesions caused by HPV in men.⁵¹ A spokesperson for Merck told the media that an FDA approval process is presently underway.⁵² While, like the studies of Gardasil for women, the studies could not determine conclusively whether Gardasil was effective in preventing cancer (here, anal and penile cancers) due to the length of time it takes from the initial development of the HPV infection to the development of cancer, the clinical studies did demonstrate that Gardasil was successful in preventing both the lesions and the infection.⁵³ Anna

⁴⁸*Id.*, but see Judith Sites-Poisson, *Women in Government, Merck’s Trojan Horse: Part Three in a Series on the Politics and PR of Cervical Cancer*, CENTER FOR MEDIA & DEMOCRACY, July 10, 2007, <http://prwatch.org/node/6232> (“Following the executive order, allegations regarding connections between Perry and Merck became public, ‘It turned out that Perry’s former chief of staff is now a lobbyist for Merck. Did that look bad? Whoa, Nellie. Did it look bad that Merck had funded an organization of women legislators backing similar bills? Whoa, Merck.’”)

⁴⁹Nat’l Conference of State Legislatures, *supra* note 45.

⁵⁰*Id.*, see also HPV Vaccine: Introduced Legislation 2008-2009 <http://www.ncsl.org/programs/health/HPVvaccine.htm#2009leg> (chart indicating state-by-state legislative action regarding the vaccine).

⁵¹Chitale, *supra* note 7.

⁵²*Id.*

⁵³*Id.*

Guiliano, M.D., who led Merck's study of the vaccine, affirmed the connection between the HPV infection and cancers in men.⁵⁴

While not nearly as prevalent as cervical cancer, the National Cancer Institute reports that 1,200 new cases of penile cancer and 2,000 new cases of anal cancer are diagnosed annually in men in the United States.⁵⁵ Giuliano says that 80-90% of those anal cancers and 40% of penile cancers are a result of HPV.⁵⁶ For women, though, the connection between HPV and cervical cancer is obvious. Women tend to see abnormal Pap smears between 2-4 years after becoming infected, whereas men are unlikely to be diagnosed with penile or anal cancer until they are much older- a typical diagnosis will occur between ages 50 and 80.⁵⁷ James Turner, M.D., professor of clinical internal medicine at the University of Virginia and chair of the Vaccine Preventable Disease Committee for the American College Health Association believes this will make convincing men to get the vaccine more difficult.⁵⁸ Laurie Markowitz, an epidemiologist and head of the CDC working group on HPV, does point out that there is already some interest in Gardasil among select male populations- namely college-aged men and gay men.⁵⁹ This interest could help spur lawmakers into making the vaccine mandatory for young men as well as women.

Part IV: Can/Should Gardasil be made mandatory for men?

⁵⁴*Id.*

⁵⁵*Id.*

⁵⁶*Id.*

⁵⁷*Id.* at 223.

⁵⁸*Id.*

⁵⁹*Id.*

Just as Merck faced opposition when it introduced Gardasil for women onto the United States market, it is likely to experience the same, if not more, when it begins to market Gardasil for men. It will likely have to overcome both legal and ethical concerns before it is able to gain support for making the vaccine mandatory for all school children, both male and female. The legal opposition tends to come in the form of equal protection arguments. While it may appear as if the battle over whether vaccines can legally be made mandatory has already been fought and won, there are several unique characteristics about HPV and Gardasil which make this fight a slightly different one. Ethical arguments against the vaccine being made mandatory for men range from the idea that a vaccine for a sexually transmitted disease promotes promiscuity, to the unfairness of making men get a vaccine for a disease that primarily effects women.

A. Legal Arguments

i. Constitutional concerns

Opposition to state regulation of vaccines has generally stemmed from arguments that the mandatory vaccinations violate the due process clause of the Constitution seen in the 14th Amendment.⁶⁰ Generally, states have been able to regulate the requirement of vaccines within their states under their general “police powers.” While traditionally difficult to define,⁶¹ a state

⁶⁰U.S. Const. amend. XIV. § 1., (“No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.”).

⁶¹See *e.g.*, *Berman v. Parker*, 348 U.S. 26 (1954), (Justice William O. Douglas explained, “An attempt to define its reach or trace its outer limits is fruitless, for each case must turn on its own facts.”); *Jacobson v. Massachusetts*, 197 U.S. 11, 25, (defining police power as “a power which the state did not surrender when becoming a member of the Union under the Constitution.”).

derives its police powers from the Tenth Amendment. The Tenth Amendment leaves the states the power to regulate matters of health, safety and general welfare of the public.⁶²

The Supreme Court first faced the question of whether requiring mandatory vaccinations is a constitutional use of a state's police power in *Jacobson v. Massachusetts*. In *Jacobson*, a Massachusetts citizen challenged a state law requiring citizens to be immunized for smallpox. There, the court defined the reach of the state's police powers, explaining that, "[I]n every well-ordered society charged with the duty of conserving the safety of its members, the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand."⁶³ The court further explained that mandatory vaccines are legal because, "[t]here are manifold restraints to which every person is necessarily subject for the common good."⁶⁴ The *Jacobson* court upheld a state legislature's decision that smallpox vaccines were "necessary for the public health or public safety," even where that decision was actually made by an appointed board of health.⁶⁵ While the court did not go so far as to hold that medical exemptions to mandatory vaccination laws were necessary, it did discuss that mandating vaccinations for those who may have an adverse reaction to the vaccination would be "cruel and inhuman to the last degree."⁶⁶

⁶²Carrie A. Roll, *The Human Papillomavirus Vaccine: Should it be Mandatory or Voluntary?*, 10 J. Health Care L. & Pol'y 421, 428-29 (2007).

⁶³*Jacobson v. Massachusetts*, 197 U.S. 11 at 29.

⁶⁴*Id.* at 26.

⁶⁵*Id.* at 27.

⁶⁶*Id.* at 38-39.

The Court expanded the reach of *Jacobson* in *Zucht v. King*.⁶⁷ In *Zucht*, the court expanded the police power to cover state orders requiring compulsory vaccination before a child may attend school. In defending compulsory vaccinations for schoolchildren, the court rejected claims that these laws violated the equal protection clause because they targeted only school children and not the entire population. The court explained, however, that “[a] long line of decisions by this court had also settled that in the exercise of the police power reasonable classification may be freely applied, and that regulation is not violative of the equal protection clause merely because it is not all-embracing.”⁶⁸

The court rejected arguments that mandatory vaccination laws violate the First Amendments right to practice religion freely in *Prince v. Massachusetts*. The court explained that, “[a]gainst these sacred private (religious) interests, basic in a democracy, stand the interests of society to protect the welfare of children, and the state's assertion of authority to that end, made here in a manner conceded valid if only secular things were involved.”⁶⁹ The Court further reasoned that although parents may become martyrs acting against the state in matters of their own health, that does not mean that they can choose to make martyrs of their children, since these children have not yet reached the age where they are capable of making such a decision for themselves.⁷⁰

Beyond due process concerns, some have argued that mandatory vaccinations violate a

⁶⁷*Zucht v. King*, 260 U.S. 174 (1922).

⁶⁸*Id.* at 176-77.

⁶⁹*Id.* at 165.

⁷⁰*Prince v. Massachusetts*, 321 U.S. 158, 170 (1944).

different part of the 14th Amendment- the equal protection clause. They argue that forcing only women to be vaccinated for a disease which is spread by both men and women is unfair, particularly since vaccines are successful only if they achieve “herd immunity,” meaning a level of immunity which is high enough to prevent the disease from being spread at all.⁷¹ Studies have failed to reach a consensus as to what percent of a population must be vaccinated in order to achieve “herd immunity,” but this percent typically ranges from 75% to 90% of the population.⁷² Even if 75% is a generous estimate, any percent over 50% would require men to be vaccinated if herd immunity is to be achieved.⁷³ Thus, many argue that men should be vaccinated in order to achieve this herd immunity, and to guarantee that statutes do not single out women unfairly in violation of the Equal Protection Clause. Doing so, however, would result in what has been called a form of “reverse equal protection.”⁷⁴ The equal protection clause “cannot provide for an artificial and fictional parity by having those who are not really equals or similarly circumstanced become equals.”⁷⁵ Since the male and female biological makeup is so inherently different, forcing men to get vaccinated in order to create so-called “fictional parity” may be illegal.

In *Adams v. Milwaukee*, the court addressed a similar concern.⁷⁶ *Adams* upheld an

⁷¹Nicki Daniels, *Boys should be vaccinated too*, The Times (U.K.), Oct. 27, 2006, at 10 (2006 WLNR 18651650).

⁷²Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. Davis Law Review 1731, 1762 (June 2008).

⁷³*See id.*

⁷⁴RENE B. GOROSPE, CONSTITUTIONAL LAW: NOTES AND READINGS ON THE BILL OF RIGHTS, CITIZENSHIP AND SUFFRAGE, 412 (Rex Bookstore, Inc. 2006).

⁷⁵*Id.*

⁷⁶*Adams v. City of Milwaukee*, 228 U.S. 572 (1933).

ordinance regulating the sale of milk which allegedly discriminated between milk drawn from cows inside the city and those outside the city. The court held that the regulations were not discriminatory, since they were properly related to the purpose which the ordinance sought to accomplish.⁷⁷ Since females are primarily affected by HPV through the development of cervical cancer, so long as statutes are narrowly drawn and emphasize the need to prevent cervical cancer, not the HPV infection generally, statutes which only mandate Gardasil for females are likely to be upheld under equal protection challenges.

Despite the case law establishing the constitutionality of mandatory vaccination laws, opponents of making Gardasil mandatory for women have pointed out that HPV is inherently different from the diseases that the vaccines in the aforementioned cases were designed to prevent.⁷⁸ Whereas smallpox or measles, both diseases traditionally covered by mandatory school-entry vaccinations, are transmitted through the air, HPV is transmitted through sexual contact.⁷⁹ Gail Javitt, J.D., a research scholar with the Berman Institute of Bioethics at Johns Hopkins University further explains that, "This vaccine is different...in that your risk is influenced by your behavior and is not equally distributed."⁸⁰ States may push back on these arguments, however, by pointing to their ability to control sexually transmitted infections as part

⁷⁷*Adams* at 581-82. See also *Miller v. Wilson*, 236 U.S. 373, 384 (1915) ("[The legislature] is free to recognize degrees of harm, and it may confine its restrictions to those classes . . . where the need is deemed to be clearest.").

⁷⁸See Richard K. Zimmerman, *Ethical Analysis of HPV Vaccine Policy Options*, 24 Vaccine 4812, 4815 (2006).

⁷⁹*Id.*

⁸⁰Chitale, *supra* note 7.

of their public health power.⁸¹ Gardasil is also different in the sense that preventing an outbreak of HPV has not been deemed a “medical necessity.” Mandating Gardasil, however, while not a medical necessity, may be a practical one. If people do not choose to protect themselves by taking adequate precautions against the disease, then “legally compelled immunization is the only practical way to combat the disease effectively.”⁸²

ii. Parental Concerns

Another legal barrier Merck will have to face when trying to convince lawmakers to make Gardasil mandatory for men is the issue of informed consent. In 1994, Senior Attorney Dave Benor of the Office of General Counsel for the U.S. Department of Health and Human Services acknowledged that for mandatory vaccines, “there is no opportunity for informed consent, given that state law at federal urging requires that [children] take these vaccines.”⁸³ In *Allison v. Merck*, a mother brought suit against Merck and her county Health District after her son allegedly suffered from blindness, deafness, mental retardation, and other ills as a result of the measles, mumps and rubella (MMR) vaccine.⁸⁴ In a footnote, the court explained that the mother “never

⁸¹See e.g., *Stadium Book & Video, Inc. v. Miami-Dade County*, 2006 WL 2374740 (upholding state interest in regulating video stores in order to prohibit the spread of sexually transmitted infections), *Ex Parte Fowler*, 184 P.2d 184 (1947) (upholding legislation authorizing local health officers to examine those arrested for crimes of vagrancy, prostitution, rape or other sex crimes to determine if they are infected with venereal disease, as a valid exercise of police power) (But note, these cases deal with quarantines, and not vaccinations).

⁸²Note, *Toward a Twentieth Century Jacobson v. Massachusetts*, 121 HVLR 1820 (May 2008).

⁸³Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. Pharmacy & L. 249, 255 (1995-96)

⁸⁴*Allison v. Merck*, 878 P.2d 948, 951 (Nev. 1994).

had any real choice” when deciding whether to give her son the vaccine.⁸⁵ Courts have, however, been willing to uphold cases where informed consent was seemingly lacking, based on the information the vaccine manufacturer provided in its package insert, even though parents are not often given the opportunity to read these inserts.⁸⁶

Beyond informed consent concerns, parents may object to any attempts to make Gardasil mandatory for men based on the more broad principle of parental choice. The Supreme Court has held that, “[t]he child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations.”⁸⁷ Courts have not had trouble holding that this right of parental choice may be overridden when the child’s life is at stake, however they have been less apt to impose upon parents medical treatments where the child’s life is not at stake.⁸⁸ While one could argue that a child’s life may be at stake if they acquire HPV, there is no guarantee that they will acquire the infection in the first place. Instead, a court is likely to find that while certainly beneficial, Gardasil is not in fact life-saving and thus states may not be able to override parental concerns in mandating it.⁸⁹

⁸⁵*Id.* at FN9. (“Not only was she, let us say, “strongly encouraged” to make the decision to go ahead with her child's vaccination, she was faced with the Hobson's choice of either having the vaccine administered or not having the privilege of sending her son to private or public school...Choosing not to have her son attend school, of course, would have subjected her to criminal penalties unless she had the means to have her son educated at home. Even if the Allison could be seen to have been properly warned of the risk inherent in this vaccine, it is hard to conclude that they freely accepted the risk of the horrible injuries resulting in this case.”)

⁸⁶*See Mazur v. Merck*, 964 F.2d 1348, 1362 (3rd Cir. 1992).

⁸⁷ *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925).

⁸⁸ *Law*, *supra* note 72 at 1767.

⁸⁹ *Id.*

iii. Opting out

States have satisfied concerns about parental choice by providing parents with broad opt-out powers. These opt-out provisions typically allow for parents to opt-out of immunizations for medical or religious reasons. By January of 1998, all states allowed for medical exemptions.⁹⁰ In order to qualify for a medical exemption, most states require a letter or documentation from a physician.⁹¹ All states grant medical exemptions for children who have an allergy to the vaccine, a compromised immune system, or a similar condition.⁹² Opting out for religious reasons is the easiest way for parents to avoid mandatory immunization laws. Almost all states offer religious exemptions to vaccinations, and a handful of states offer “philosophical exemptions” as well.⁹³ These exemptions are granted virtually “on demand,”⁹⁴ however, each state defines its exemption differently. For example, in Texas, one must submit a letter from a faith leader, whereas in California, all that is necessary is a parental affidavit.⁹⁵

While allowing parents to opt-out of vaccinations on behalf of their children may satisfy parental choice concerns, some believe that opting out is dangerous for the rest of society. A

⁹⁰Daniel A. Salmon et al., *Health Consequences of Religious and Philosophical Exemptions from Immunization Laws: Individual and Societal Risks of Measles*, 282 *Journal of the American Medical Association* 47, 47 (1999).

⁹¹*Id.* at 48.

⁹²Jason L. Schwartz, Commentary, *Unintended Consequences: The Primacy of Public Trust in Vaccination*, 107 *Mich. L. Rev. First Impressions* 100 (2009), <http://www.michiganlawreview.org/firstimpressions/vol1107/schwartz.pdf>.

⁹³Donald G. McNeil Jr., *Worship Optional: Joining a Church to Avoid Vaccines*, N.Y. TIMES, Jan. 14, 2003, at F1.

⁹⁴*Id.* (Noting that the American Journal of Public Health found in 2000 that only 21 of the 47 states had ever denied a request for a religious exemption).

⁹⁵Salmon, *supra* note 89 at 48.

study done of data collected by the Measles Surveillance System of the CDC found that, on average, exemptors were 35 times more likely to contract the disease than vaccinated individuals.⁹⁶ The study concluded that the incidence of the measles infection would increase greatly as the population of exemptors in a particular region increased.⁹⁷ Additionally, the last two polio outbreaks in the United States took place in Amish and Mennonite communities during the 1970s and similar measles outbreaks have occurred in Christian Science and Amish schools in the 1980s.⁹⁸

b. Ethical Arguments

Even if Gardasil were to surmount the legal barriers which are currently making it more difficult for states to make it mandatory for men, there are a variety of ethical concerns that will likely be raised as well, ranging from concerns about fairness to both male and female patients, to questions about the correlation between the vaccination and promiscuous behavior, to concerns about the cost and marketing of the drug.

i. Questions of fairness

Similar to the concerns raised in the equal protection discussion above, many have argued that only making Gardasil for female children in order to enter public schools is simply unfair to those female children. They point to the connection between HPV and sexual contact.⁹⁹ Even a

⁹⁶*Id.* at 47.

⁹⁷*Id.* (“Specifically, the study found that if the number of exemptors doubled, the incidence of measles infection in nonexempt individuals would increase by 5.5%, 18.6%, and 30.8%, respectively, for intergroup mixing ratios of 20%, 40%, and 60%”).

⁹⁸McNeil, *supra* note 92.

⁹⁹Daniels, *supra* note 71.

monogamous woman is at risk due to any of her partner's previous sexual relationships.¹⁰⁰

While these concerns about fairness are legitimate, one must also consider: is it fair to vaccinate men just to make things more “fair” for women? Currently, the Gardasil vaccine involves some degree of risk. Primarily, the vaccine has not been around long enough to determine its long term effects. It is unclear as to whether the young age at which it is administered will result in the need for booster shots later in life.¹⁰¹ The FDA's Patient Information About Gardasil lists pain, swelling, itching, and redness at the injection site, headache, fever, nausea, dizziness, vomiting, and fainting as the most common side effects of the immunization.¹⁰² While these may not be the most troublesome side effects, they are worth considering when doing a cost-benefit analysis regarding whether giving Gardasil to men is worth the risk. Also important to consider are the less common, but more serious adverse events that have been reported to the FDA following Gardasil injections. Although Merck notes that “[b]ecause these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure,”¹⁰³ they are still worth considering when deciding whether males should be given the Gardasil vaccine. The more serious side effects reported have ranged from death, to autoimmune disease, to paralysis and seizures.¹⁰⁴ Because of these side effects, the National Vaccine

¹⁰⁰*Id.*

¹⁰¹Roden & Wu, *supra* note 20, at 756.

¹⁰²Food & Drug Association, USPPi Patient Information About Gardasil, <http://www.fda.gov/cber/label/gardasilppi.pdf>

¹⁰³Food & Drug Association, Gardasil Package Insert, <http://www.fda.gov/cber/label/gardasilLB.pdf>

¹⁰⁴*Id.*

Information Center has been vocal in its opposition to the vaccine.¹⁰⁵ They report that there are 29 known cases of young patients dying after receiving the vaccine, based on the Vaccine Adverse Events Reporting System compiled by the FDA.¹⁰⁶ Men may find that these risks associated with the vaccine are too high to justify the benefit of the prevention of penile and anal cancers, especially when those cancers occur infrequently.

iii. Focusing only on gay men

Getting men vaccinated will also be difficult because doctors have hypothesized that it is gay men who are most in need of the vaccine.¹⁰⁷ A study of men who seek male sexual partners in Australia found that these men were strongly in favor of the vaccine.¹⁰⁸ However, it would be difficult to target the vaccine only at the subset of the male population who seeks homosexual partners. Like only giving the vaccine to girls, it seems unfair to only give the vaccine to homosexual men. If heterosexual men are carriers as well, one could argue that they should be equally encouraged to be vaccinated. Only advocating that homosexual men become vaccinated is also problematic because doctors encourage vaccination *before* one's sexual debut.¹⁰⁹ Males between ages 9-11, the age when Gardasil is recommended to be given to females, are unlikely to be comfortable talking to their doctor about their sexual preferences, so it will be very difficult

¹⁰⁵Post of Erin Brown to NewsBusters.com blog, *Post Article Largely Ignores Health Problems With Gardasil Vaccine*, <http://newsbusters.org/blogs/erin-brown/2009/03/26/post-article-largely-ignores-health-problems-gardasil-vaccine> (March 26, 2009).

¹⁰⁶*Id.*

¹⁰⁷*See* Devamalar Simatherai, et al., *What men who have sex with men think about the human papillomavirus vaccine*, Sex. Transm. Inf. (January 2009)

¹⁰⁸*Id.*

¹⁰⁹*Id.*

for doctors to ascertain whether one male should get the vaccine over another.

iii. Promotion of promiscuity

Perhaps the greatest ethical opposition Gardasil for men will face, like Gardasil for women, is the argument that a vaccination for a sexually transmitted disease will promote promiscuity in young teenagers.¹¹⁰ Some fear that the vaccine will encourage more sexual activity among partners, increased numbers of partners, and less use of other forms of protection.¹¹¹ This may result in more unplanned pregnancies, abortions, and other forms of sexually transmitted infections.¹¹² Opponents fear that the vaccine may send the message, 'We expect you to be sexually active,' to teens said Reginald Finger, a doctor trained in public health who served as a medical analyst for Focus on the Family.¹¹³ A state representative in California went so far as to say that the money spent on Gardasil should be spent on other vaccines- emphasizing that cervical cancer involves a lifestyle choice, whereas other cancers are a result of unlucky genetics.¹¹⁴ Some believe that such concerns about promiscuity (as well as parents beliefs that their children will remain abstinent until marriage) will cause many parents to oppose the vaccine.¹¹⁵

¹¹⁰Rob Stein, *Cervical Cancer Vaccine Gets Injected with a Social Issue*, Wash. Post, Oct. 31, 2005, at A3.

¹¹¹Zimmerman, *supra* note 79, at 4813.

¹¹²*Id.*

¹¹³Stein, *supra* note 107.

¹¹⁴Meghan O'Rourke, *Cancer Sluts: Does the HPV Vaccine "Promote" Promiscuity?*, SLATE, September 27, 2007, <http://www.slate.com/id/2174850/>.

¹¹⁵See R. Alta Charo, *Politics, Parents, and Prophylaxis--Mandating HPV Vaccination in the United States*, 356 New Eng. J. Med. 1905, 1907 (2007).

Despite this opposition by parents who believe their children will not become sexually active and thus advocate abstinence-only sex education rather than the vaccine, studies have shown that abstinence programs do not delay the onset of sexual activity in teenagers, nor do they reduce the number of sexual encounters that these teenagers will engage in.¹¹⁶ Studies regarding condom availability have similar results. Adolescents who are provided with condoms are no more likely to engage in more sexually activity as a result than those who were not provided with condoms.¹¹⁷ Others have emphasized that it is improbable that HPV will be a significant deterrent for teenage sexual behavior. Whereas STDs like herpes or gonorrhea have immediate effects, the effects of HPV are so far removed from the sexual activity itself that teenagers are unlikely to make the connection between the vaccination and the ability to have more sexual encounters without risk.¹¹⁸ It is also important to note that the vaccinations are not given to young adults merely to prevent the spread of HPV amongst that age group. Vaccinations are meant to have life-long effects, and vaccinating eleven to fourteen year olds may simply be the most efficient way to achieve these life-long effects.¹¹⁹

¹¹⁶*Id.*

¹¹⁷Ann Quigley, *School Condom Availability Does Not Increase Sexual Activity*, CTR. FOR THE ADVANCEMENT OF HEALTH, May 28, 2003, <http://www.hbns.org/news/condom05-28-03.cfm>. (However, the condom availability *did* result in those teenagers who were already engaging in sexually conduct becoming more likely to use those condoms).

¹¹⁸O'Rourke, *supra* note 111.

¹¹⁹See Cynthia Dailard, *Achieving Universal Vaccination Against Cervical Cancer in the United States: The Need and the Means*, 9 Guttmacher Pol'y Rev. 12, 14 (2006), *see also* James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 869-73 (2002) (discussing rubella and hepatitis B vaccinations as examples of vaccinations given to children whose effects are often not seen until later in life).

Approximately 80 percent of deaths from cervical cancer worldwide occur outside the United States,¹²⁰ where arguments connecting Gardasil with promiscuity will most likely have a greater impact. In countries where discussing female sexual behavior is more taboo, some suggest that it may in fact be easier to have boys vaccinated than girls.¹²¹ Anne Szarewski, of from the charity Cancer Research UK notes that, "We found that some Asian women in Britain are afraid even to get tested for HPV infection, because they say if it is positive they will be killed, never mind that their husbands probably gave it to them."¹²²

An alternative to Gardasil which may be able to surmount the opposition based on a fear of promoting promiscuity is the yet-to-be-approved Cervarix vaccine, currently being developed by GlaxoSmithKline.¹²³ Unlike Gardasil, Cervarix will not prevent genital warts.¹²⁴ Since it is focused solely on preventing cervical cancer, GlaxoSmithKline hopes it will be able deflect some of the criticism from those who fear Gardasil will defeat their efforts to promote abstinence.¹²⁵ Unfortunately for GlaxoSmithKline, however, by the time its vaccine reaches the market, Gardasil will have already been alone in the market for approximately 16 to 19 months or more,

¹²⁰Debra MacKenzie, *Will Cancer Vaccine Get to All Women?*, NewScientist, Apr. 18, 2005, at 8, available at <http://www.newscientist.com/article/mg18624954.500-will-cancer-vaccine-get-to-all-women.html>.

¹²¹*Id.*

¹²²*Id.*

¹²³Ben Hirschler, *Glaxo Says Cervarix to Transform the Vaccine Business*, REUTERS, May 27, 2005, available at <http://www.signonsandiego.com/news/business/biotech/20050527-0200-health-glaxo-vaccines.html> (last visited Mar. 29, 2009).

¹²⁴*Id.*

¹²⁵*Id.*

depending on the FDA approval process.¹²⁶

Marketing Gardasil to men may receive less criticism based on concerns about promiscuity as marketing it to women did. Susan M. Reverby, a professor of women's studies and medical history at Wellesley College, points out that, “We are still more worried about the promiscuity of girls than the promiscuity of boys.”¹²⁷ The debate surrounding Gardasil for men has already focused more attention on issues such as the vaccine’s cost and the risks associated with administering it, rather than promiscuity, when compared to the debate that occurred when the vaccine was introduced for women.¹²⁸ Only time will tell if this bias will continue following FDA and CDC approval of the vaccine for men.

iv. Cost

It may also be difficult to get men vaccinated against the HPV virus because the current cost of Gardasil is prohibitively high for some. Currently, the vaccine costs approximately \$360 for the necessary three doses.¹²⁹ Unfortunately, the age group which would receive the most benefit from the vaccine, eleven to fourteen year olds, are the least likely to be able to afford the vaccine.¹³⁰ Whereas infants born in hospitals are likely to receive proper health care and vaccinations due to the hospitals standards of care, and older teenagers are able to get health care from family planning clinics, the eleven to fourteen year olds who have the most to benefit from

¹²⁶*See supra* note 22.

¹²⁷Rob Stein, *A Vaccine Debate Once Focused on Sex Shifts as Boys Join the Target Market*, THE WASHINGTON POST, March 26, 2009, at A01.

¹²⁸*See id.*

¹²⁹Amy Gardner, *Drugmaker Assists in Pushing for Mandate for HPV Vaccination*, Wash. Post, Feb. 11, 2007, at C5.

¹³⁰Law, *supra* note 72 at 1747.

the vaccine may not have regular visits to a health care provider.¹³¹ Even those with private health insurance may have a hard time paying for the vaccine, due to prohibitively high co-payments and deductible costs,¹³² and the number of insurance providers refusing to cover to the costs of vaccinations.¹³³

Gardasil's high cost has led some to question whether men should be asked to bear the burden for the cost of women's health. While some seem open to the idea,¹³⁴ the significantly lower cancer rates among males who have contracted HPV may be too low to justify the cost for most men, especially when cheaper alternatives such as condoms, abstinence and male circumcision are available to at-risk groups.¹³⁵ However, assuming the vaccine is recommended by ACIP for men as it has been for women, those who can not afford the vaccine on their own may receive public funding. Both Medicaid, and the federally-funded VCF Program may cover the vaccine along with all other ACIP-approved vaccinations for individuals under 21 who

¹³¹*Id.*

¹³²Rebecca Gudeman, *High Cost of HPV Vaccine Limits Use in Surprising Way: The Problem with Private Insurance*, 28 Youth L. News 1, 2 (2007), available at http://www.youthlaw.org/fileadmin/ncyl/youthlaw/publications/yln/2007/issue_2/YLN_APR_JUN_Article_1.pdf.

¹³³See Zimmerman, *supra* note 80, *see also* Comm. on Child Health Fin., Am. Acad. of Pediatrics, *High Deductible Health Plans and the New Risks of Consumer-Driven Health Insurance Products*, 119 Pediatrics 622, 622 (2007) (From 2003 to 2006, the number of employee sponsored plans which did not cover vaccinations increased from 5% to 20%).

¹³⁴Jan Hoffman, *Vaccinating Boys for Girls' Sake?*, N.Y. TIMES, Feb. 24, 2008, available at 2008 WLNR 3619620, ("That's good enough for some mothers. "If there was a vaccine I could take that would get rid of prostate cancer, why wouldn't I?" said Lisa Lippman, a Manhattan real estate broker with three sons. "If there was a vaccine that sons could get that would get rid of breast cancer, most parents wouldn't hesitate. But cervical cancer is the 'sex cancer.' ")

¹³⁵See Roden & Wu, *supra* note 20, at 761.

qualify for the programs.¹³⁶ However, the states are often asked to bear the burden of these federally mandated health programs, and it is unlikely that most states will have the funding to cover such a high volume of vaccinations.¹³⁷ Inclusion in these programs may also give private insurance companies an excuse not to cover the shots, since they will assume the states will cover them.¹³⁸

A large-scale cost-benefit analysis may still reveal that the vaccine is worth its cost when examined alongside overall healthcare costs. Currently, the HPV infection amounts to somewhere between \$2.25 and \$4.6 billion in healthcare costs per year.¹³⁹ However, since Gardasil does not cover all types of HPV, it may be important to continue the costly screening process already in place, thus reducing some of the positive cost-reducing effects of the vaccine.¹⁴⁰

v. Marketing

While Merck has been hugely successful in marketing the vaccine to women,¹⁴¹ that same success may ultimately be its biggest hurdle in getting men interested in becoming vaccinated.

¹³⁶Roll, *supra* note 62, at 441-42 (The Vaccines for Children Program applies to children 18 and under who are: (1) Medicaid eligible; (2) uninsured; (3) underinsured; or 4) Native American or Alaska Natives.).

¹³⁷*Id.*

¹³⁸*Id.*

¹³⁹Hoffman, *supra* note 128, *but see supra* note 21(20?), (“Estimates of the global market value for HPV vaccines are that it will be worth \$2 billion to \$4 billion within three years).

¹⁴⁰Roden & Wu, *supra* note 20 at 759.

¹⁴¹Judith Sites-Poisson, *Research, Develop & Sell, Sell Sell: Part Two in a Series on the Politics and PR of Cervical Cancer*, CENTER FOR MEDIA & DEMOCRACY, June 30, 2007, <http://prwatch.org/node/6208>

To market Gardasil, Merck garnered the help of public relations superstar Edelman.¹⁴² Edelman is the world's largest independent public relations firm; they generated \$299 million in revenues in 2006.¹⁴³ Edelman is known for its role in creating partnerships between business and non-profits, and it has worked with the tobacco industry, companies facing environmental disasters, and most of the world's largest pharmaceutical companies.¹⁴⁴ Their work for Merck has garnered the company numerous accolades- they received the Public Health Award at the PhAME Awards ("the first and most comprehensive awards ceremony focusing on pharmaceutical consumer marketing and communications"), and the website *Pharmaceutical Executive Magazine* selected Gardasil as its brand of the year.¹⁴⁵

Gardasil's advertisements have been aimed solely at young women and their mothers, and its "one less" campaign seemed to be everywhere.¹⁴⁶ For several months, it was difficult to turn on the television and not run into female skateboarders and jump-ropers chanting "O-N-E-L-E-S-S. I want to be one less. One less."

Despite the campaign's success among advertising industry professionals, it may ultimately backfire. "[Parents] didn't see it as having much benefit for their sons," said Dr. Kharbanda, an adolescent specialist at New York-Presbyterian/Columbia University Medical

¹⁴²*Id.*

¹⁴³*Id.*

¹⁴⁴*Id.*

¹⁴⁵*Id.*

¹⁴⁶See Laurie Peterson, *Merck to Women: 'Get Vaccinated,' Be 'One Less' Cancer Statistic*, MARKETING DAILY, November 14, 2006, http://www.mediapost.com/publications/index.cfm?fuseaction=Articles.showArticle&art_aid=51097.

Center. “It was smart of Merck to get people excited about it for the girls, but now they’re stuck with that perception.”¹⁴⁷ Merck may have an especially difficult time encouraging men to get vaccinated since its advertisements have made a point of avoiding all discussion of the connection between Gardasil and genital warts.¹⁴⁸ The lack of understanding of that connection, combined with the significantly lower number of instances of anal and penile cancers in men as a result of the HPV infection and Merck’s advertisements which have made Gardasil a “girl’s vaccine” will make it difficult for them to garner the same degree of hype to get men vaccinated as it did for women.

vi. Anti-vaccination trend

Finally, there is a growing trend of parental opposition to all vaccines generally which will likely play a role in preventing men from choosing to be vaccinated against HPV. This trend, led by well-known public figures such as Congressman Dan Burton, Robert F. Kennedy Jr. and actress Jenny McCarthy, has emphasized speculations regarding a possible link between vaccinations and diseases such as autism.¹⁴⁹ These arguments typically gain force due to the present low instances of diseases such as polio or measles which children are typically vaccinated against. Health officials emphasize, however, that continued vaccination is the only way to continue to keep these diseases at bay.¹⁵⁰

¹⁴⁷Hoffman, *supra* note 128.

¹⁴⁸Rebecca E. Skov, *Examining Mandatory HPV Vaccination for All School-Aged Children*, 62 Food & Drug Law Journal 805, 812 (2007).

¹⁴⁹See note 73 *supra*, at 100-01.

¹⁵⁰*Id.* at 101-02.

Organizations such as the Anti-Vaccination League of America are growing as well. Groups like these tend to have two main reasons for opposing vaccinations: some believe that mandatory vaccinations amount to a sort of “medical tyranny,” similar to religious or political tyranny, while others believe that vaccinations prevent health risks which are much greater than the FDA and the pharmaceutical industry wants us to believe.¹⁵¹ Those that believe mandatory vaccinations are a form of medical tyranny point to the fact that the European countries with the highest levels of immunization have reached those levels without making vaccines mandatory.¹⁵² This argument may not have much force. The United States differs from these European countries in two significant respects: (1) the United States lacks a comprehensive healthcare system, and (2) the United States lack universal health insurance.¹⁵³

Part V: What should be done?

As a result of these barriers, Merck will have several options when it officially begins to market the Gardasil vaccine to men. First, it may seek to encourage state and federal legislators to treat both men and women the same for vaccination purposes, requiring the vaccine before school entry for all children, not just females. Alternatively, if this proves to be too burdensome, based on equal protection and due process concerns, they may be better off simply educating and incentivizing men to get vaccinated, without going so far as to make it mandatory. Taking this

¹⁵¹See Note, *supra* note 83, at 1823.

¹⁵²Daniel A. Salmon et al., *Compulsory Vaccination and Conscientious or Philosophical Exemptions: Past, Present, and Future*, 367 *Lancet* 436, 440 (2006).

¹⁵³Law, *supra* note 72.

route appears as if it will be the more successful although less lucrative one, as it will allow Merck to tailor its message to men differently than it has for women, and will allow it to focus on the most at-risk subset of the male population, homosexual men.